K130211

510(k) Summary

JUL 5 2013

SUBMITTER INFORMATION:

SPSmedical Supply Corp.
a division of Crosstex International
6789 West Henrietta Road
Rush, NY 14543 U.S.A.
Phone: (800) 722-1529
Fax: (585) 359-0167

Contact Person:	Michael Nolan Research and Development Coordinator
Date of Summary:	July 5, 2013

DEVICE INFORMATION:

Device Trade Name:	AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets
Common Name:	Bowie Dick Test Pack and Bowie Dick Indicator Sheets
Device Classification:	Indicator, Physical/Chemical Sterilization Process 21 CFR § 880.2800
Device Class:	2
Product Code:	JOJ

PREDICATE DEVICE:

AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets K041017

DEVICE DESCRIPTION:

The SPSmedical AirView™ Bowie Dick Test Pack is a disposable device which is intended for use as a replacement for the ANSI/AAMI ST79 Bowie Dick Test Pack. The SPSmedical AirView™ Bowie Dick Indicator Sheets are designed to be used within the ANSI/AAMI ST79 Bowie Dick test pack

INTENDED USE:

The SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets are designed to detect the presence of residual air in pre-vacuum steam sterilizers operating at 134°C. The Bowie Dick test pack and indicator sheets are reliable tools used for the monitoring of air removal in steam pre-vacuum processes and provides a visual indication if residual air was left in the chamber during sterilization. Its internal indicator sheet changes to a uniform dark brown/black signal color under proper sterilization and air removal conditions. A failure would result in a non-uniform color change on the indicator sheet.

TECHNICAL CHARACTERISTICS:

The layers of paper within the SPSmedical AirView™ Bowie Dick Test Pack provide resistance to steam penetration and also trap air between them which is difficult for marginal performing pre-vacuum sterilizers to remove.

RECOMMENDED STORAGE CONDITIONS:

Store in a cool, dry place (15-30°C)

510(k) Summary (Continued)

INTERFERING SUBSTANCES OR CONDITIONS:

Testing verified that the indicators in their unprocessed form are not sensitive to an acidic or basic environment. Testing verified that the indicators in their processed form are not sensitive to an acidic or basic environment.

SHELF LIFE:

The Shelf Life of the SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets shall be three (3) years from the date of manufacture, when stored in a cool, dry place (15-30°C)

BIOCOMPATIBILITY:

The purpose of a biocompatibility test is to demonstrate that the active ingredients of the chemical indicator do not release any substance known to be toxic onto surgical instruments. Although the SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets are intended to be run in an empty chamber it was necessary to address this concern. Biocompatibility testing on the indicators concluded that the SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets were non-toxic.

SUBSTANTIAL EQUIVALENCE ANALYSIS

SPSmedical has identified the AirView™ Bowie Dick Test Pack & AirView™ Bowie Dick Indicator Sheets (K041017) as the (primary) predicate device. We believe the predicate device to be substantially equivalent to the AirView™ Bowie Dick Test Pack & AirView™ Bowie Dick Indicator Sheets which is the subject of this submission in terms of their intended use and functional characteristics in determining the effectiveness of air removal in pre-vacuum steam sterilizers.

FUNCTIONAL CHARACTERISTICS:

The SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets are designed to detect the presence of residual air in pre-vacuum steam sterilizers operating at 134°C. The layers of paper within the pack provide resistance to steam penetration and trap residual air which is difficult for marginal performing pre-vacuum sterilizers to remove. The pack is a reliable tool used for the monitoring of air removal in pre-vacuum steam sterilizers and provides a visual indication if residual air was left in the chamber during sterilization. The indicator sheet changes from its initial color to a uniform dark brown/black signal color under proper sterilization and air removal conditions. A failure would result in a non-uniform color change on the indicator sheet.

DISCUSSION:

SPSmedical is claiming substantial equivalence for its SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets to the original AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets (K041017) based on test data obtained during validation studies. We have demonstrated with testing that the SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets perform consistently with results which indicate that the indicator is sensitive enough to detect when enough air is left within the sterilizer chamber to create a 2°C or greater temperature difference in the test pack as compared to the sterilizer chamber when running pre-vacuum sterilization at 134°C. Under these conditions, the indicator sheet would demonstrate a non-uniform color change. The SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets are also comparable to other commercially available Bowie Dick test packs cleared by the FDA. See examples of similarly cleared devices in Tab 8.

510(k) Summary (Continued)

SUBSTANTIAL EQUIVALENCE CONCLUSIONS:

The SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets have the same intended use and characteristics as the primary predicate device (K041017). They both provide a visual indication that proper air removal and steam penetration conditions have been met within the sterilizer's chamber. Both products are comprised of paper sheets, foam, a containment box or wrap, external chemical indicator label and printed indicator sheet.

SPSmedical believes that the SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets are substantially equivalent to the predicate device because it has the same intended use, technical characteristics and performance. Because the ability to perform its intended function as been shown through validated testing, the SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets raise no issues related to safety or effectiveness and therefore, the device should be allowed for market in the United states. See Table 1 below for a substantial equivalence comparison.

TABLE 1—COMPARISON OF THE MODIFIED DEVICE TO THE PREDICATE

Element	Modified Device	Predicate (K041017)
Intended Use	Air Removal Indicator	Air Removal Indicator
Device Design	Bowie Dick Test Pack or Sheet	Bowie Dick Test Pack or Sheet
Endpoint Color	Dark Brown/Black	Dark Brown/Black
Indicator Agent	Indicator Ink	Indicator Ink
Sterilization Method	Steam Pre-vacuum	Steam Pre-vacuum
Device Materials	Equivalent	Equivalent
Air Porosity	Equivalent	Equivalent
Performance under standard fault condition	Equivalent	Equivalent
Performance under standard Bowie Dick cycle	Equivalent	Equivalent
Shelf Life	Three (3) years	Three (3) years

CONCLUSION:

Supportive data has demonstrated that the SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets are equivalent to the predicate device. The SPSmedical AirView™ Bowie Dick Test pack and AirView™ Bowie Dick Indicator Sheet raise no issues related to safety or effectiveness and therefore should be allowed for market in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 5, 2013

SPS Medical Supply Corporation
C/O Mr. Michael Nolan
Research and Development Coordinator
6789 West Henrietta Road
RUSH, NY 14543

Re: K130211
Trade/Device Name: AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: May 30, 2013
Received: June 7, 2013

Dear Mr. Nolan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

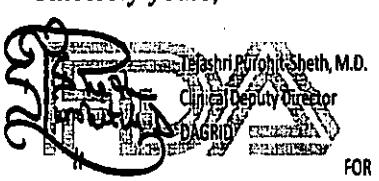
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health'

Enclosure

Statement of Indications for Use

510(k) Number (if known): K130211

Device Trade Name: AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets

INDICATIONS FOR USE:

The SPSmedical AirView™ Bowie Dick Test Pack and AirView™ Bowie Dick Indicator Sheets are designed to detect the presence of residual air in pre-vacuum steam sterilizers. When tested in a pre-vacuum sterilizer operating at 134°C the indicator will demonstrate a uniform color change from cream or blue to dark brown/black when proper sterilization conditions have been met and no air is detected. It is designed to be used for daily Bowie Dick testing of steam sterilizers as described in ANSI/AAMI ST79.

Prescription Use _____ and/or Over the Counter Use __X__

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Elizabeth F. Claverie
2013.06.28 21:36:53 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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